

Notice of Allowability

Application No.

09/533,427

Examiner

Anne-Marie Falk, Ph.D.

Applicant(s)

CHIORINI ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after final amendment filed 11/14/03.
2. ☒ The allowed claim(s) is/are 1,2 and 11-17.
3. ☒ The drawings filed on 22 March 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Anne-Marie Falk
 Anne-Marie Falk, Ph.D.
 Primary Examiner
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EXAMINER'S AMENDMENT

The amendment filed November 14, 2003 has been entered. Claims 2, 12, and 13 have been amended.

Claims 1, 2, and 11-17 remain pending.

The following informal Examiner's amendments were made February 17, 2004. Authorization from Applicants is not required. See MPEP 1302.04.

The application has been amended as follows:

In the Specification:

On page 9, line 6, replace "Figure 12 shows" with --Figures 12A and 12 B show--.

On page 9, line 15 replace "Figure 13 shows" with --Figures 13A-F show--.

On page 9, line 26, replace "Figure 14 shows" with --Figures 14A-D show--.

On page 10, line 5, replace "Figure 15 shows" with --Figures 15A-D show--.

On page 10, line 14, replace "Figure 16 shows" with --Figures 16A and 16B show--.

On page 11, line 14, replace "Figure 20 shows" with --Figures 20A-C show--.

The following is an examiner's statement of reasons for allowance:

The rejection of Claims 2, 12, and 13 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendments to the claims.

The rejection of Claims 11, 14, and 15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,180,613 (Kaplitt et al., filed June 6, 1995) and Georg-Fries et al. (1984) is withdrawn in view of Applicants' argument at the top of page 8 of the response filed October 6, 2003, which refers to a lack of knowledge of the tropism of AAV5. Although others in the field writing around the same time as the filing date of the Kaplitt et al. patent, spoke of the various AAV serotypes as being interchangeable

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(see e.g., USPN 5,843,742, column 7, lines 5-7), later publications, such as Chiorini et al. (1999, *J. Virol.* 73(2): 1309-1319), demonstrated differences in tissue tropism that would have led one of skill in the art to recognize that in fact the different AAV serotypes were not interchangeable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1, 2, and 11-17 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (571) 272-0548.

Anne-Marie Falk, Ph.D.

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ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER